

K063039

510k Summary

1. **Submitter:** Imaging Dynamics Company Ltd
Suite 151, Pegasus Way NE
Calgary, AB,
Canada T2E 8M5
- NOV - 2 2006
- Contact person:** Shirantha Samarappuli
Manager - Regulatory Affairs
Tel: 403 251 9939; Fax: 403 251 1771
- Date Prepared:** Oct 30, 2006
2. **Device Name:** Xplorer 2200 Digital Radiographic System,
3. **Device Classification:** Class II, 892.1630 (MQB), 892.1680 (KPR), 892.1980 (IZZ)
4. **Predicate Device:** Xplorer 1600 Digital Radiographic System (K042041)
5. **Device Description:** The Xplorer 2200 is a combination of two Xplorer 1000 CCD imagers, a previously marketed device covered by 510k K992955. One imager is in the Xplorer 1100 radiographic table, a previously marketed device covered by 510k K062417 and the other imager is on a vertical stand, a previously marketed device covered by 510k K062405. The system is operated in conjunction with a ceiling mounted X-ray tube/collimator assembly. The Xplorer 2200 system is manufactured by Imaging Dynamics. The CCD Imagers are unchanged from that which is marketed under K992955.
6. **Indications for Use:** The Xplorer 2200 is intended for use by a qualified/trained doctor or technologist on both adult and pediatric patients for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts on both adult and pediatric patients. Applications can be performed with patient sitting, standing or lying in the prone or supine positions. The Xplorer 2200 (510k submission device) is not intended for mammography.
7. **Comparison with predicate device:** The Xplorer 2200 is substantially equivalent to the currently marketed Xplorer 1600. Xplorer 2200 device does not alter the fundamental scientific technology from Xplorer 1600 predicate device. The only modification attributed is the integration of Xplorer 2200 (510K Submission device) system which includes Xplorer 1590 Digital radiographic stand (K062405), Xplorer 1100 patient table (K062417) with Xplorer digital radiographic detector (K992955) and ceiling mounted x-ray tube/collimator assembly. Xplorer 2200 has the same intended use as the predicate device.
- a. Non-clinical tests: The device has been evaluated for performance, biocompatibility and effectiveness as well as thermal, electrical and mechanical safety and has been found to substantially equivalent to predicate device. The design and development process of the manufacturer conforms to 21 CFR part 820. ISO 9001 and ISO 13485 quality systems.
 - b. Clinical tests: No clinical tests conducted.
 - c. Conclusion: The device was evaluated against the predicate device (Xplorer 1600 - K042041) for all performance, safety & effectiveness requirements and found as substantially equivalent to the predicate device.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Ms. Shirantha Samarappuli
Manager-Regulatory Affairs
Imaging Dynamics Co., Ltd.
Suite 151, 2340 Pegasus Way NE
Calgary, Alberta, T2E 8M5
CANADA

AUG 23 2013

Re: K063039

Trade/Device Name: Xplorer 2200 digital radiographic system
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB and KPR
Dated: September 29, 2006
Received: October 3, 2006

Dear Ms. Samarrappuli:

This letter corrects our substantially equivalent letter of November 2, 2006.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

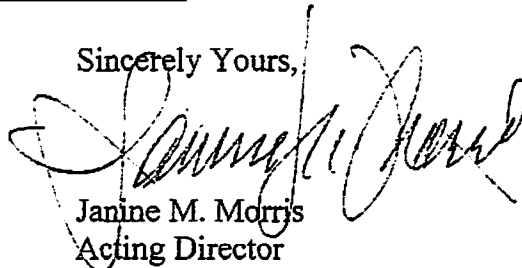
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

**Special 510k Submission
Xplorer 2200 Digital Radiographic System**

Indications for Use

510(k) Number (if known): K063039

Device Name: Xplorer 2200 digital radiographic system

Indications for Use:

The Xplorer 2200 is intended for use by a qualified/trained doctor or technologist on both adult and pediatric patients for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts on both adult and pediatric patients. Applications can be performed with patient sitting, standing or lying in the prone or supine positions.

The Xplorer 2200 (510k submission device) is not intended for mammography.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063039